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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,018	10/19/2001	Dong Huang	P444 0003	7140

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,018

Applicant(s)

HUANG, DONG ET AL.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3, 7-10, 12, 14, 16-23, 25 and 27-69 is/are pending in the application.
- 4a) Of the above claim(s) 35-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 7-10, 12, 14, 16-23, 25 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Acknowledgement is made of the response filed in paper no. 8 and 9. Amendments are entered (except 0040). Claims 1-3, 5, 7-10, 12, 14, 16-23, 25 and 27-69 are pending. Arguments were fully considered but are not found persuasive therefore rejection over Hasegawa et al. (Abstract of JP 08291194) and Park, Ki (WO 97/31933) is maintained for the same reasons as set forth in our previous office action. Rejection under 35 U.S.C. 112, second paragraph is withdrawn because claims are amended. New claims 35-69 are independent and not examined.

Presently claimed invention is drawn to sapogenins and saponins of dammarane series. Sapogenins with no hydroxyl group at C-20 compared to sapogenins that have a hydroxyl group at C-20 are claimed to be surprisingly more effective in cancer treatment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8, 14, 16-23, 25, rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been

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described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: Instant invention is directed to saponins and sapogenins of dammarane series and their method of use for the treatment of cancer.

The state of the prior art: No compound has ever been found that can treat cancers generally even though massive efforts have been directed towards this end. Nearly all-anticancer drugs are effective against only a limited group of related cancers. Therefore, a compound effective against cancer generally would be a revolutionary exception.

The predictability or unpredictability of the art: There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Therefore predicting which compounds within the broad genus will be useful is impossible.

The amount of direction or guidance presented There is no drug, which is broadly effective against all forms of cancer, (see Carter S.K. et al. *Chemotherapy of Cancer*, pages 364 and 365; second edition, John Wiley & sons, New York, 1981, appendix C). See table on pages 364 and 365 where the interaction of different drugs on various type of cancer are listed. It is clear from the data that each drug has different interactions with different types of tumors i.e. one drug cannot treat all type of cancer. See *In re Fisher*, 427 F.2d

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833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity).

See also *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), this is because it is not obvious from the disclosure of one species, what other species will work.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The quantity of experimentation necessary

Since different aspects of biological activity cannot be predicted but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue experimentation study. Since the nature of the method is so unpredictable, and since the claims are drawn to a broad range of pharmaceuticals for treatment of such a broad range of disease states, and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

The amendment filed in paper no. 8, para [0040] is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

See last two lines of amended para {0040} where Preferable reaction temperature is added which was not in the original specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

Claims 1-3, 5, 7-10 12, 14, 16-23, 25 and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al., Yun et al. and Sung Won Kwon et al. See the entire documents. All the references cited above teach dammarane sapogenins and saponins, which embraces Applicant's claimed invention.

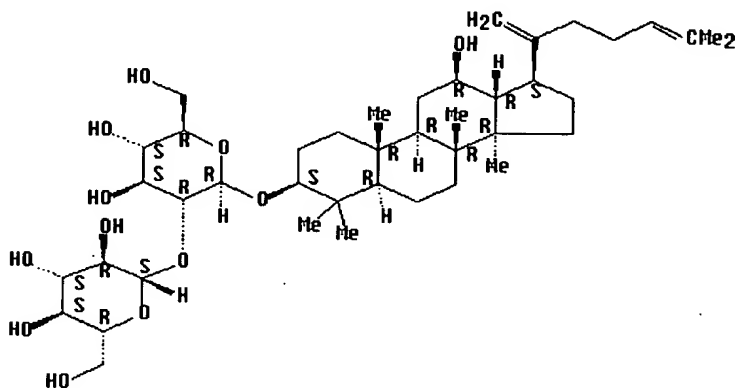
1. Determining the scope and contents of the prior art.

Park et al. teach ginseng saponins for multidrug resistance, see the entire document and structure of compounds cited above. Sang-Kwon et al teaches the ginsenoside Rg3 inhibition on multi drug resistance, see the entire document especially page 336 where anticancer activity of the ginsenosides are disclosed; Yun et al. teaches anticarcinogenic effect and identification of active compound, Ginsenoside Rg3, Rg5 and Rh2 were found to be active anticarcinogenic compounds and they are said to prevent cancer either singularly or synergistically, see the abstract, Tables 1-8, fig. 1-3 and compounds on page S 13; Park teach ginseng saponin compounds and their use as antitumor agent. Similar sapogenins and saponins as positional isomer (double bond at different position in the side chain attached at 17-

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poaiton) is instantly claimed. See compound at page S13, Rg5 in Yun et al. which has the following structure.

This compound and its method of use are presently claimed.



2. Ascertaining the differences between the prior art and the claims at issue.

Instant claims drawn to compounds and method of use differs from the references in claiming a different position of double bond in the side chain at 17-position. Even though by disclaiming certain compounds for anticipation, instant invention is considered obvious over the prior art, because instant invention is the positional isomer of the prior art.

3. Resolving the level of ordinary skill in the pertinent art.

Since presently claimed compounds are the positional isomer of the prior art, or saponins are known one having ordinary skilled in the art in search for additional dammarane sapogenins or saponins

One skilled in the art would be motivated to isolate or prepare such compounds and would expect anticancer activity. Cleavage of sugar from saponins to get sapogenins is conventional and is known to one skilled in the art. This would not be a patentable distinct matter.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Since instant sapogenins and saponins are isolated from ginseng as in instant invention and posses anticancer and multi resistance properties which is considered obvious to one skilled in the art at the time of invention to prepare isomers and expecting the same properties which is taught by the prior art for similar compounds. In absence of showing any criticality or unexpected results presently claimed invention is considered obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on every business day..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



SABIHA QAZI, PH.D
PRIMARY EXAMINER